JUL 20 2011

510(k) Summary, K102401

Sponsor:	Vilex in Tennessee, Inc., 111 Moffitt St., McMinnville, TN 37110, 931-474-7550
Contact:	Sylvia Southard Date: July 8, 2011
Device Name:	Cannulated Metallic Hemi Implant
Classification:	21 CFR 888.3730 – Toe joint phalangeal (hemi-toe) polymer prosthesis, KWD
Predicate Devices:	K023684 Vilex Cannulated Metallic Hemi Implant K041595 BioPro Hemi Joint with optional coating K911378 Townley Great Toe Joint8: BioPro K084369 Metasurg Hemi Joint K081876 OsteoMed Resurfacing Metatarsal Implant with HA Coating K971047 FUTURA Biomedical
Description of Device:	Vilex Cannulated Metallic Hemi Implant is a one-piece device intended to resurface the base of the proximal phalanx. It is similar in design to the predicate devices (BioPro K023684) and MetaSurg (K083469) in terms of articular surface shape and fixation. Implants will be offered in cobalt chrome or titanium, with or without Hydroxyapatite (HA) coated stem and back as an option.
Material:	Cobalt chrome molybdenum alloy or Titanium Ti6Al4V (optional). The implant may be cemented to the phalanx or press-fit without cement.
Indications for Use:	The Vilex cannulated metallic hemi implant, a hemi-arthroplasty implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; Hallux Limitus, Hallux Valgus, Hallux Rigidus, and an unstable or painful MTP joint. The Vilex cannulated metallic hemi implant is intended to be used with bone cement or press fit without bone cement. The Vilex cannulated metallic hemi implant is intended for single use only.
Non-Clinical Test Data	Based on the engineering analysis, the Vilex implants are equivalent to predicates in terms of mechanical integrity and resistance to bending torques.
Substantial Equivalence:	Documentation is provided which demonstrates that the Vilex Implants are substantially equivalent to other legally marketed devices with and without HA coating. The methods used to establish equivalence are comparisons of indications for use, materials of construction, sizes, shapes, and mechanical integrity analysis.
Establishment Reg. No.:	1051526

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Vilex, Inc.
% Ms. Sylvia Southard
111 Moffitt Street
McMinnville, TN 37110

JUL 20 2011

Re: K102401
Trade/Device Name: Vilex Cannulated Metallic Hemi Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: July 8, 2011
Received: July 14, 2011

Dear Ms. Southard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102401

Device Name: Vilex Cannulated Metallic Hemi Implant

Indications for Use:

The Vilex cannulated metallic hemi implant, a hemi-arthroplasty implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; Hallux Limitus, Hallux Valgus, Hallux Rigidus, and an unstable or painful MTP joint.

The Vilex cannulated metallic hemi implant is intended to be used with bone cement or press fit without bone cement.

The Vilex cannulated metallic hemi implant is intended for single use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for N. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102401